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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,895	03/31/2004	Tomoko Takeshita	HIRA.0147	5008
7590 REED SMITH LLP Suite 1400 3110 Fairview Park Drive Falls Church, VA 22042			EXAMINER NOBLE, MARCIA STEPHENS	
			ART UNIT	PAPER NUMBER
			1632	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/06/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/812,895

Applicant(s)

TAKESHITA ET AL.

Examiner

Marcia S. Noble

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 10, 11, 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 13, 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/2006 has been entered.

Status of Claims

2. Claims 10, 11, 13, and 14 are pending. Claims 10, 11, 13, and 14 are amended and claims 12 and 15 are canceled by the request for continued examination, filed 12/27/2006. Claims 10, 11, 13, and 14 are under consideration.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

5. Claims 10-15, rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, have been amended and no longer recites the new matter, "an identical depth". Therefore the rejection is rendered moot.

New Matter

6. Claims 10, 11, 13, and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Amended claims 10 and 13 recite "wherein relative to a vertical axis". There is no literal or figurative support for this recitation in the specification. Amended claims 11 and 14 recite "identical to an injection amount and injection area in all others of the oocytes". The specification does not provide literal support for this recitation. In Applicant's remarks, filed 12/27/2006, they state that this recitation has support on pages 9 and 10 of the specification. Pages 9 and 10 provide an automated process of injecting into the animal hemisphere of a plurality of oocytes, therefore, there is some figurative support for "identical to an injection area". However, the specification also states that injection into the animal hemisphere can be made for about 80% of oocytes (p. 10, last two lines). This suggests that the area of injection is also not identical

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because 20% of the oocytes receive the injection in a different injection area. Amended claim 13 recites "an interaction". There is not literal support for this recitation and because of its great breadth is unclear as to what "an interaction" is referring.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 10, 11, 13, and 14 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

The amended claims recite "relative to a vertical axis". "A vertical axis" is not defined in the specification and an oocyte is spherical, therefore an artisan would not know what would be considered the vertical axis in the instant invention. Furthermore, since "a vertical axis" is being used in the claims as a relative point of injecting RNA, an artisan would not know how to orient the oocyte "relative to a vertical axis" as claimed.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner

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should conclude that the claimed subject matter is not described in that application.

MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure" (emphasis added).

Claim Rejections - 35 USC § 112, 2nd paragraph, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 13 and 14 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 10 was rejected for its "mRNA which is respectively injection", which has deemed indefinite. This recitation has been removed by amendment, therefore, rendering this rejection moot.

Amended claim 13 stands rejected as being indefinite because the relationship between the claimed solution and sample is not clear, in part due to a lack of antecedent basis. Claim 13 still recites the limitation "a sample" in line 1; "a solution" in line 10, and "the solution containing said sample" in line 12. The method is screening "a sample", however the adding step of line 10 adds a solution. This solution has no link to the said sample of the claims. As recited it may or may not have the sample of interest.

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The following measuring step recites "the solution containing said sample". The claim lacks clear antecedent basis for "the solution containing said sample" because it is unclear if the previous solution contains sample or not. Applicant did not address this rejection in their remark and did not amend this recitation. Therefore, the rejection is maintained.

Claim 13 also recites, "measuring an electrical response...thereby discriminating". The metes and bounds of this recitation are indefinite because it is unclear how is being discriminated. Claim 14 depends from claim 13.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 10, 11, 13 and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al (5,688,938). Claims 13 and 14 have been amended and no longer are anticipated by the instant art. Therefore, the rejection of claims 13 and 14 is withdrawn.

Applicant traverses this rejection on the grounds that the claims have been amended to recite all the features of the amended claims.

Applicant's arguments are found partially persuasive.

As previously stated in the Final Office Action, mailed 8/28/2006, claims 10-12 are drawn to a product that requires an oocyte with mRNA injected into its cytoplasm.

As long as the product has the same components it can be produced by any means. Brown discloses oocytes with an mRNA injected into its cytoplasm, thereby meeting the limitations of the claims (see p. 9, par 1 of Final Office Action). Therefore, because Brown et al still teach the limitations of the claims, the rejection of claims 10 and 11 are maintained.

Furthermore, the claim 10 and 13 recite "wherein relative to a vertical axis and an animal hemisphere of each amphibian oocyte being positioned in an upward direct". This dictates that positioning of the oocyte but it does not disclose where the injection must occur. The claim 10 and 13 further recite, "mRNA positioned in a cytoplasm thereof at a depth relative to the vertical axis in the range of 0.02-0.1 mm from a top surface". These recitations define a positioning of the oocyte and a depth at which the RNA is positioned presumably by injection. This recitation does not specify an injection site. As previously stated in the new matter rejection, the specification does not define "a vertical axis" or "a top surface". Therefore a vertical axis can be interpreted as any axis because the oocyte is a sphere. Similarly a top surface is also relative on an oocyte because again the oocyte is a sphere so any surface on the oocyte will qualify as a top surface. Therefore, because a vertical axis and top surface are relative and be any axis or any surface, the disclosure by Brown et al of an injection in the vegetal pole with the same depth as disclosed in the instant claims encompass the limitations of the instant claims.

Therefore, because the instant amendment to the claims and applicants arguments do not overcome the rejection of record. The rejection is maintained.

Claim Objections

Claim 11 is objected to because of the following informalities: Referring to "The" subject of a previous claim, rather than "A", is proper format for a dependent claim.

Accordingly, "A plurality" in claim 11 should read "The plurality".

Appropriate correction is required.

Claim 14 is objected to because of the following informalities: Referring to "The" subject of a previous claim, rather than "A", is proper format for a dependent claim.

Accordingly, "A method" in claim 14 should read "The method".

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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9. Claims 10 and 11 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-16, 18, 21, 24 and 26-27 of U.S. Patent No. 6,593,129.

Applicant did not address this rejection and the claims still encompass the product, oocytes injected RNA into its cytoplasm. Therefore the rejection of record is maintained.

10. The rejection of claims 10 and 11 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,803,207, is withdrawn because Applicant filed a terminal disclaimer.

Applicant filed a terminal disclaimer on 11/28/2006 that was approved on 12/11/2006 to address the instant rejection. Therefore, the rejection is withdrawn.

11. Claims 10 and 11 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-16 of copending Application No. 10/876,551.

Applicant did not address this rejection. However, the amendment to claims 13 and 14 no longer have an overlapping scope with the copending claims. Therefore, the rejection of claims 13 and 14 are withdrawn.

However, Claims 10 and 11 still encompass the product, oocytes injected RNA into its cytoplasm. Therefore the rejection of claims 10 and 11 is maintained.

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble
AU 1632

Valerie Lutz
AU 1632